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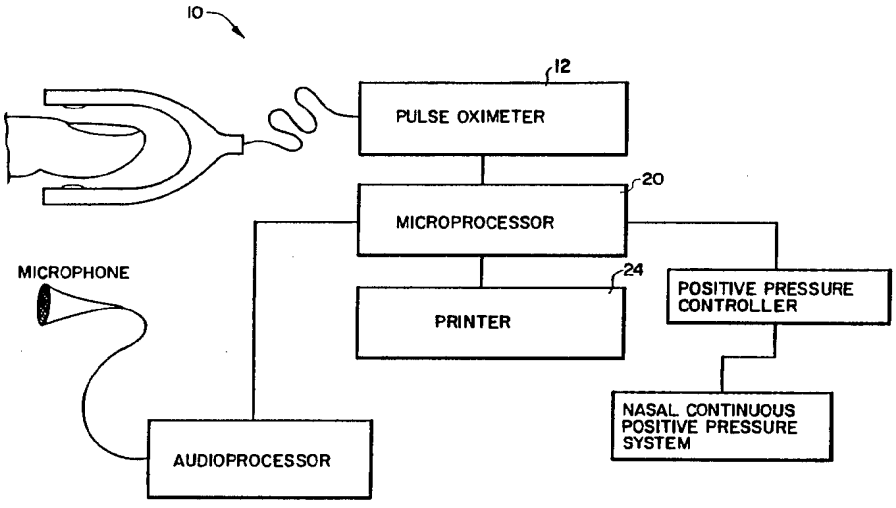

(57) Abstract

A device (10) for diagnosing sleep apnea by identifying desaturation and resaturation events in oxygen saturation of a patient's blood. The device (10) includes a probe (14) for transillumination or reflection from a human body part such as a finger (16). The device (10) is connected to a microprocessor (20) which records oxygen saturation and pulse as a function of time. A printer (24) is connected to the microprocessor (20). The microprocessor (20) analyzes the oxygen saturation values as a function of time. A desaturation event is identified as to whether or not it meets criteria for physiologic apnea. The number of events per hour are then calculated and then printed. Each desaturation event which has been identified as consistent with a physiologic apnea is so marked. The slope of the events is determined and compared against various information to determine sleep apnea.

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APPARATUS FOR THE DIAGNOSIS OF SLEEP APNEA

BACKGROUND AND SUMMARY OF THE INVENTION

Disorders of breathing during sleep are now known to constitute a major health problem throughout the world. Obstructive sleep apnea is an extremely common disease which manifests itself in variable degrees of severity. The disease develops when muscle tone of the upper airway diminishes during sleep and negative pressures associated with inspiration result in collapse of the upper airway, preventing air movement and resulting in airway obstruction. The sleeping patient inhales more forcibly, thereby, further lowering upper airway pressures and causing further collapse of the upper airway. During this time, substantially no air movement into the chest occurs and the patient becomes progressively more hypoxic and hypercarbic. Both hypoxemia and hypercarbia produce central nervous system stimulation resulting in arousal. Upon arousal, increase in airway muscle tone opens the airway and the patient rapidly inhales and ventilates quickly to correct the abnormal arterial blood gas values. Generally, the arousal is only modest and the patient is not aware of the arousal. Once blood gas parameters have been corrected, the patient begins to sleep more deeply, upper airway tone again diminishes, and the upper airway collapses resulting in sequential and cyclic apneic arousal episodes.

The duration and severity of each apnea is quite variable from patient to patient and with the same patient throughout the night. Indeed, the disease process represents a spectrum of severity from mild snoring, which is associated with incomplete and

inconsequential airway obstruction, to severe apneas which can result in fatal hypoxemia.

This disease commonly results in excessive daytime sleepiness and can disrupt cognitive function during the day due to fragmentation of sleep during the night associated with recurrent arousals of which the patient is not aware.

Although this disease commonly affects obese patients, it may occur in patients with any body habitus. Because this disease is so common and because it presents with the subtle and common symptoms of excessive daytime sleepiness, morning headache, and decreasing ability to concentrate during the day, it is critical that an inexpensive technique for accurately diagnosing and treating this disease be developed. Traditionally, this disease has been diagnosed utilizing a complex and expensive multi-channel polysomnogram. This is generally performed in a sleep lab and involves the continuous and simultaneous measurement and recording of an encephalogram, electromyogram, extraoculogram, chest wall plethysmogram, electrocardiogram, measurements of nasal and oral air flow, and pulse oximetry. These, and often other, channels are measured simultaneously throughout the night and these complex recordings are then analyzed to determine the presence or absence of sleep apnea.

The problem with this traditional approach is that such complex sleep testing costs between one-thousand to thirty five hundred dollars. Since sleep apnea is so common, the cost of diagnosing obstructive sleep apnea in every patient having this disease in the United States would exceed Ten Billion Dollars.

It is critical that a new, inexpensive technique of accurately diagnosing sleep apnea be developed.

Nocturnal oximetry alone has been used as a screening tool to screen patients with symptoms suggestive of sleep apnea to identify whether or not oxygen desaturations of hemoglobin occur. Microprocessors have been used to summarize nocturnal oximetry recordings and to calculate the percentage of time spent below certain values of oxygen saturation However, oxygen desaturation of hemoglobin can be caused by artifact, hypoventilation, ventilation perfusion mismatching. For these reasons, such desaturations identified on nocturnal oximetry are not specific for sleep apnea and the diagnosis of sleep apnea has generally required expensive formal polysomnography.

The present invention comprises a system and technique for deriving and utilizing the analysis of graphical pulse oximetry-derived waveforms as a function of time to accurately diagnosis sleep apnea with adequate specificity to, in many cases, eliminate the need for expensive formal polysomnography.

It is the purpose of this invention to provide an inexpensive system for the collection and analysis of pulse oximetry values as a function of time during sleep to provide a diagnosis of sleep apnea with a high degree of specificity.

This invention provides a reliable and specific means for the diagnosis of obstructive sleep apnea which can be performed in the patient's home without attendance of technical personnel. It is further the purpose of this invention to provide an inexpensive and accurate means to both screen for and specifically

diagnose obstructive sleep apnea by a single overnight recording in the patient's home without the need for multiple connections to different parts of the patient's body. It is further the purpose of this invention to define a technique for diagnosing obstructive sleep apnea utilizing the calculation of the ascending and descending slope ratio of phasic oxygen desaturations measured during sleep.

Specifically, the present invention defines a device for diagnosing sleep apnea, that has the following components. First, a means must determine an oxygen saturation of a patient's blood. This saturation value is coupled to a means for identifying a desaturation event based on the saturation value. The desaturation event is one in which said oxygen saturation falls below a baseline level by a predetermined amount and for a predetermined time. The slope of the event is calculated by means for calculating a slope of said desaturation event representing a rate of change per unit time of fall of oxygen saturation. This slope is used by a means for comparing said calculated slope with a value of slope which is determined in advance to be indicative of sleep apnea, and determination of diagnosis of sleep apnea is made based on said comparing.

The comparing can be done by:

1) comparing with an absolute number which is likely to indicate a sleep apnea, or

2). comparing with other slopes taken at different times.

The identifying means can also identify a resaturation, immediately following said desaturation and coupled with said desaturation, in which the

oxygen saturation rises, and wherein the determination can also be based on a slope of said resaturation.

Many other ways of calculating the slope are also disclosed herein.

These and other aspects of the invention will now be described in detail with reference to the accompanying drawings, wherein:

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a block diagram of the basic system of the present invention;

Figure 2 shows a basic flowchart of operation of the present invention;

Figures 3 and 4 show basic desaturation events and many of the parameters associated therewith;

Figure 5 shows a specific way in which a comparison can utilize the calculation of the area above each desaturation event compared to area above each coupled resaturation event.

Description of the Preferred Embodiments

The inventor of the present invention found, relative to sleep apnea diagnosis, that the waveform pattern of oximetry during a sleep recording can be considered in relation to the physiologic parameters which affect oxygen saturation over time. Specifically, during an apneic period, arterial oxygen saturation initially falls as a function of the oxygen saturation of mixed venous blood and oxygen uptake from residual exchangeable oxygen within the lungs. Subsequently, arterial oxygen saturation falls directly as a function of oxygen consumption and

global oxygen stores. These stores of oxygen are very limited. The sources of oxygen available during an apneic period include residual exchangeable oxygen within alveoli and airways, the oxygen bound to hemoglobin, dissolved oxygen within body tissues and oxygen stored as myoglobin. These stores are rapidly depleted during an apneic period as a function of global oxygen consumption. As oxygen stores are depleted, the cellular oxygen levels fall, and mixed venous oxygen saturation progressively diminishes. Since a small amount of exchangeable oxygen supply exists within alveoli and airways, arterial oxygen saturation, as measured by the pulse oximeter is briefly unaffected by the initial fall in body oxygen storage. However, since oxygen stores within the alveoli are extremely limited, arterial oxygen saturation then progressively falls toward that of mixed venous arterial blood saturation since little significant gas exchange occurs as mixed venous blood passes by essentially unventilated alveoli. The partial pressure of oxygen in arterial blood therefore progressively falls toward the mean partial pressure of oxygen in body tissues at the cellular level.

It is possible to measure indirectly the partial pressure of oxygen in arterial blood by measurement of arterial oxygen saturation of hemoglobin utilizing a pulse oximeter 12. If the probe 13 of pulse oximeter is placed on a patient's finger or other body part during a prolonged apneic period, a progressive decrement in arterial saturation will be identified as a function of the fall in arterial oxygen partial pressure. Although the initial decline in arterial oxygen saturation is

greatly dependant on mixed venous oxygen saturation, since body oxygen stores during a apnea cannot be repleted, the subsequent portion of the fall in arterial oxygen saturation as measured by a pulse oximeter over time will be directly correlated to the oxygen consumption of the patient. The average oxygen consumption of a resting human (approx. 3.5 ml/kg/min) has a relatively constant relationship to average body arterial oxygen stores (approx. 25 ml/kg). Although substantial variability exists in body oxygen stores in chronically ill patients with low cardiac output states (resulting in lower mixed venous oxygen storage), a finite range of oxygen stores exists. Indeed, even in the presence of severe compensated disease, mixed venous oxygen saturation generally ranges from 50% - 80%. Therefore, a sleeping human has a definable and predictable range of slopes of arterial oxygen saturation decrement as a function of the baseline mixed venous oxygen saturation initially and of oxygen consumption and body oxygen stores terminally. Although augmented body muscular activity associated with obstructive apnea could modestly increase oxygen consumption and although a decrease in oxygen consumption may occur below a critical levels of tissue oxygenation, the declining range of slope of desaturation is still predictable within only modest variances.

To understand the predictable parameters of arterial pulse oximetry waveform, it is important to consider the way in which pulse oximetry reflects total body oxygen stores. Total body oxygen stores can be conceived as representing four major compartments:

1. The Lung Compartment,
2. The Arterial Compartment,
3. The Tissue Compartment, and
4. The Venous Compartment.

Oxygen enters the lungs and is stored sequentially in each of these compartments. When oxygen is depleted during apnea, depletion occurs first in the tissue compartment, second in the venous compartment, third in the lung compartment, and fourth in the arterial compartment. Whereas, when oxygen is repleted, oxygen appears first in the lung compartment, second in the arterial compartment, third in the lung compartment, and fourth in the venous compartment. It can be seen, therefore, that since pulse oximetry measurements reflect oxygen stored within the arterial compartment, if sequential depletion of arterial saturation occurred due to phasic apneas that the initial apneic episode would result in depletion of the arterial compartment only after the substantial depletion of other compartments has developed.

Using the above, the inventor of the present invention realized that he could predict with reasonable certainty whether or not a desaturation occurring during a continuous nocturnal oximetry measurement falls within the anticipated range of parameters which define the slope of arterial oxygen desaturation of hemoglobin which can physiologically occur during an apneic episode. In this manner, each desaturation episode can be defined, as a function of the characteristics of the waveform of deflection, as either consistent with an apneic episode or inconsistent with an apneic episode. Saturations which decrease too rapidly to be accounted for on the

basis of physiologic oxygen depletion due to apnea would be identified as inconsistent with an apneic episode and therefore identified as being secondary to artifact. On the other hand, the desaturation episodes which decrease too slowly to be accounted for on the basis of physiologic oxygen depletion and would be identified as inconsistent with an apneic episode and therefore secondary to either hypoventilation, alterations in ventilation perfusion matching, or to artifact. The means for identifying a desaturation event is preferably a processor; and according to the first embodiment of this invention, as described above, the processor compares a calculated slope of the event with a value of slope which is determined in advance to be indicative of sleep apnea. A diagnosis of sleep apnea is made based on that comparison.

More specifically, the preferred embodiment of the sleep apnea diagnosis system 10 of the present invention is shown in Figure 1. It includes a conventional pulse oximeter (12) with a probe (14) for transillumination or reflection from a human body part such as a finger (16). The oximeter is connected to a microprocessor (20) which records oxygen saturation and pulse as a function of time. A printer (24) is connected to the microprocessor. The microprocessor analyzes the oxygen saturation values as a function of time, as will be discussed in detail herein. In one preferred embodiment, the system is used in the following way:

The microprocessor is disposed in connection with the oximeter with a probe and printer for recording the oxygen saturation as a function of time, and the oximeter probe is attached to a patient. The

oxygen saturation of hemoglobin is recorded as a function of time while the patient sleeps.

A measurement interval of, for example, 10 minutes is defined along the sleep recording as shown in step 200 of Figure 2. Step 202 defines a mean maximum baseline range of oxygen saturation of hemoglobin (± 3% saturation) is defined over the measurement interval.

A desaturation event can be defined as at least a 4% substantially uninterrupted decrement in saturation below the defined baseline mean of oxygen saturation. A lower percentage can be used to increase sensitivity. Each desaturation event is identified in step 204, and the desaturation change of each desaturation event is measured. The desaturation interval is defined as the duration of the uninterrupted decline in saturation of each desaturation event.

Then, slopes are calculated. The descending slope of each desaturation event is calculated as:

$$\Delta S_D / \Delta T_D$$

where:

ΔS_D = Desaturation change (in % saturation;

ΔT_D = Desaturation interval (in seconds).

A resaturation event is defined as a substantially uninterrupted rise in saturation which terminates the declining slope of the desaturation event. The resaturation change of each resaturation event is also measured.

The resaturation interval is measured as the duration of the uninterrupted rise in saturation of each resaturation event. The ascending slope of each resaturation event is calculated as:

$$\Delta S_R / \Delta T_R .$$

where:

ΔS_R = Resaturation change (in % saturation);

ΔT_R = Resaturation interval in seconds.

A phasic desaturation event is defined using all coupled desaturation and resaturation events wherein the sum of the duration of the desaturation event and the resaturation event is less than 3.5 minutes and wherein the descending slope falls within a finite range of between 1.3%/sec and 0.3%/sec.

The descending to ascending saturation slope ratio of each phasic desaturation event is calculated as:

$$(\Delta S_D / \Delta T_D) \; / \; (\Delta S_R / \Delta T_R) .$$

The number of probable apneic events within the measurement interval is defined as the number of phasic desaturation events falling within the finite range of ascending to descending slope ratios of between 3.5 - 10.5.

Each probable apneic event is marked with the identity marker, *PA*, and the above steps are repeated for each additional 10 min. interval along the recording for the entire sleep recording.

Then, appropriate action is taken: either the pulse oximetry waveform is printed as a function of time with each probable apneic event marked *PA* for

identification, or treatment of sleep apnea is either manually or automatically administered.

The probability that a patient has sleep apnea will be a direct function of the number of phasic desaturations which meet the above criteria for sleep apnea per hour of recording and this probability can be calculated and printed.

Therefore, in the preferred embodiment, each desaturation event is identified as to whether or not it meets the criteria for physiologic apnea. The number of events per hour are then calculated and then printed. Each desaturation event which has been identified by the microprocessor as consistent with a physiologic apnea is so marked (such as *PA* for *probable apnea* or *PCA* for *physiologically consistent with apnea*). The pulse oximetry waveform in the preferred embodiment is then printed to provide a hard copy. This printed hard copy includes identification of each desaturation event which has been determined by the microprocessor as consistent with a physiologic apnea. In addition, the presence of desaturation slope acceleration, as will be discussed, by comparing closely spaced consecutive desaturation slopes as in Figure 4 and such identification also provided on the printed hard copy.

This invention therefore provides a compact, single device which is easily suitable for home use and can be simply taken home by the patient and interfaced with a body part, such as a finger, to provide both screening and a mechanism to provide a specific diagnosis of sleep apnea with a single overnight recording. The hard printed copy provides graphical data which can be overread by the physician

since the computer specifically identifies the desaturation events which have been interpreted as consistent with sleep apnea. This provides the physician with the opportunity to determine whether he or she agrees with the diagnostic interpretation of the microprocessor.

The diagnosis can be treated by repeating the sleep recording during nasal CPAP (Continuous Positive Airway Pressure) therapy. The identification of multiple desaturations with patterns as defined above which are consistent with the physiology of apnea and which are eliminated by nasal CPAP therapy is diagnostic of apnea and further establishes the parameters defining effective treatment requirements.

The invention includes the system taking additional action based on the identification of the diagnosis of sleep apnea based on the above slope comparison. The action can include, as in figure 1, the microprocessor activating a range of nasal continuous airway pressures through a pressure controller within defined limits to automatically and effectively treat a patient's sleep apnea once the diagnosis of sleep apnea has been made by the microprocessor. Activation of flow is initiated by the microprocessor on identification of multiple sleep apnea-related desaturations meeting the criteria as descried above. The pressure can be titrated upward by, for example 1-2 cm H_2O pressure increments by the microprocessor upon identification of multiple consecutive desaturations which are not effectively eliminated by the starting pressure.

In this way, the invention greatly enhances the diagnostic sensitivity and specificity of

nocturnal oximetry in the diagnosis of sleep apnea and to further utilize the identification of oximetry-derived desaturation events to trigger the storage and/or collection of additional sensory data concerning each desaturation event and; furthermore, the system can be utilized to automatically initiate and adjust therapy to mitigate further after following desaturation events.

In addition to a definable descending desaturation slope, oximetry measurements during apnea periods have other definable and predictable parameters. Importantly, apneic episodes have a definable and predictable range of duration. It is clear that brief apneic episodes, for example with brief breath holding does not result in significant arterial oxygen desaturation as measured by pulse oximetry. However, when apneic periods are prolonged as with obstructive sleep apnea, oxygen desaturation progressively declines as a function of factors, as previously discussed. Unless such an apneic episode is limited in duration, the patient would die from hypoxemia. Therefore, each desaturation which occurs as a function of apnea will have a phasic quality with a predictable range of duration. A second aspect of the invention analyzes the duration of the apneic episode to determine if it is of a duration likely to indicate sleep apnea.

The range of duration generally does not exceed three minutes. Therefore, for a desaturation event identified by pulse oximetry to be secondary to an apneic episode, it should preferably have a duration of less than three minutes. Oxygen desaturations due to sleep apnea should be terminated

with the resaturation of recovery within 3 - 3.5 minutes or less. Oxygen desaturation events which occur for greater than three minutes are identified as either secondary to hypoventilation, ventilation perfusion mismatching, or artifact.

Another aspect of the invention is based on the recognition that an apneic episode which occurs during sleep is generally reversed by an arousal. At this point, the patient's central nervous system increases upper airway tone and atmospheric gas rapidly enters the lungs and exchanges with the oxygen depleted gas within the alveoli. This exchange occurs within a few seconds. Since mixed venous blood in pulmonary capillaries rapidly equilibrates with the partial pressure of oxygen in the alveoli, arterial oxygenation will recover within seconds of the repletion of oxygen within alveoli. It should be noted that the amount of time required for blood to pass from the pulmonary capillaries to the peripheral site of pulse oximetry measurement can be measured is very brief. Therefore, the ascending slope of oxygen saturation during recovery from an apneic episode is extremely rapid. Ascending slopes which are not rapid are unlikely to be secondary to repletion of oxygen partial pressure within alveoli associated with arousal from an apneic episode and rather may be secondary to a crescendo of increasing respirations following a hypoventilation episode as in Cheyne-Stokes respirations or may be secondary to improvement in ventilation perfusion matching. In a recent study performed by the present inventor the mean slope of desaturation was 0.8% per second, with all desaturation slopes ranging between 0.3% per second

and 1.1% per second. The mean slope of recovery 7.6% per second, with recovery slopes ranging from 2.5% per second to 8.3% per second. The mean recovery to apnea slope ratio was 7.66, with a range of 3.8 to 10.4. Hence, in yet another aspect of the invention, the resaturation slope, immediately following the desaturation, is also determined, and used in the diagnosis of sleep apnea.

Additional ways of comparing the calculated slope with a value of slope which is determined in advance to be indicative of sleep apnea include using other parameters to enhance the specificity of continuous nocturnal oximetry in the diagnosis of sleep apnea include comparisons of consecutive desaturation slope values and the identification of alterations in desaturation values as a function of events occurring immediately prior to the desaturation event.

Since obstructive sleep apnea events occur by similar physiologic process each time within the same patient, consecutive desaturation events will commonly have similar desaturation slopes. The identification of these consecutive desaturation events having similar desaturation slopes which have values consistent with physiologic apnea provides additional evidence supporting these events as secondary to cyclic obstructive sleep apnea.

Furthermore, the preceding desaturation event can effect the shape and the slope of the desaturation event which immediately follows. That is, preceding desaturation event may accelerate the initial portion of the slope of the following desaturation. Although other factors may contribute

to the development of this increase in desaturation slope, the primary factor appears to be the depletion of body oxygen stores where insufficient time has developed for repletion for tissue and venous oxygen stores. In other words, during rapidly cycling apneic events, recovery time may be inadequate to replete all body oxygen stores. However, the pulse oximeter is measuring arteria oxygen saturation. Therefore, after repletion of oxygen stores within the lung, arterial oxygen saturation rapidly rises before venous oxygen stores have been repleted. If an apneic event recurs before the restoration of venous oxygen stores, this apneic event will be superimposed upon substantially depleted total body oxygen stores despite the fact that pulse oximetry may demonstrate normal arterial oxygen saturation. Since at this time apnea is occurring in the presence of markedly depleted body oxygen stores (i.e. a much lower mixed venous oxygen saturation), the initial portion of the slope of the declining arterial oxygen saturation may be substantially greater than the slope of the decline of oxygen saturation which occurred during the preceding desaturation event. This phenomenon would not be expected to occur in association with artifact and would only be expected to occur in the presence of rapidly cycling changes in body tissue oxygen stores. Consecutive closely spaced desaturation events, therefore, interact so that the first desaturation event can affect the waveform of the second desaturation event provided the interval between the two events is short enough and the level of desaturation occurring in the first event is

substantial enough to result in a sizable depletion of total body oxygen stores.

The greatest portion of oxygen storage is within the venous compartment. At any given time, therefore, the amount of global oxygen stored is, in large part, a function of the extent of excess of oxygen delivered to the tissues which is stored within the venous pool. In the absence of arterial hypoxemia or profoundly compromised cardiovascular function, oxygen delivery substantially exceeds oxygen demand, resulting in considerable oxygen stores within the mixed venous pool. The amount of oxygen stored within the mixed venous pool can, therefore, be seen as a dynamically-stored, hidden buffer which mitigates the decline in saturation attendant any change in alveolar ventilation. Although patients with profoundly decreased mixed venous oxygen saturations would be expected to have a more rapid and greater fall in arterial oxygen saturation for any given level of change in alveolar ventilation, this still falls within a definable range.

During very rapidly cycling apneas (i.e. apneas occurring within less than 10 - 20 seconds of each other), body oxygen stores can be seen therefore as a moving wave through consecutive body compartments wherein the first wave affects the configuration of the second wave. The identification of this effect should be virtually diagnostic of rapidly cycling sleep apnea and this phenomenon can be exploited to assist in the specific diagnosis of sleep apnea utilizing the recording of nocturnal oximetry alone.

Desaturation slope acceleration may occur when cyclic apneic events occur within less than 10

seconds of each other and when the depth of arterial saturation associated with the first cyclic event is greater than 15%. The inter-desaturation event intervals can be defined specifically as that point wherein the first desaturation event recovers substantially to baseline to the point in time when the second desaturation event begins to decline from the baseline.

It can be seen, therefore, that a declining waveform of arterial oxygen desaturation in severe sleep apnea can be expected to have two major physiologically-derived components: 1) the slope of the initial declining limb which is primarily a function of the level of mixed venous oxygen saturation at the onset of apnea and the amount of exchangeable oxygen in the lung remaining after the onset of apnea. 2) the second component or terminal limb is primarily a function of global oxygen consumption relative to body oxygen stores. (The terminal limb may not be present if apnea is brief.) The slope of the initial and terminal limb are generally similar in patients with normal mixed venous oxygen saturations. However, in patients with significantly low mixed venous oxygen saturation, the initial limb may have a much greater slope than the terminal limb, producing an angled appearance suggesting antecedent depletion of mixed venous oxygen stores.

The magnitude of the oxygen deficit which is derived from the preceding apneic event less the intervening excess oxygen uptake which attenuates this deficit between the apneas defines the magnitude of the slope acceleration of the initial limb of the

after-following desaturation event. Therefore, an interval of oxygen deficit is present following a sustained apnea but it is hidden since arterial oxygen saturation is normal.

Figure 3 illustrates a desaturation event and many of the parameters as discussed supra which define the event. The parameters shown include:

ΔS_D Fall in saturation (in % sat.)

ΔS_R Rise in saturation (in % sat.)

ΔT_D Duration of the fall in Saturation/desaturation (in seconds)

ΔT_R Duration of the rise in saturation/resaturation (in seconds)

$M_D = \Delta S_D / \Delta T_D$ = Mean Slope of Desaturation

$M_R = \Delta S_R / \Delta T_R$ = Mean Slope of Resaturation.

We also define the following terms:

AI The apnea interval - (the actual time wherein the patient experiences cessation of airflow which precipitates oxygen desaturation.)

OAI The occult apnea interval - (the interval wherein apnea has occurred; however, arterial oxygen stores are maintained by a shift of oxygen stores form the lung and venous compartment into the arterial compartment hiding the fall in body oxygen stores with respect to the oximetry measurement.)

OODI The occult oxygen deficit interval - (the interval immediately following return of oxygen saturation to near baseline after a desaturation event and wherein mixed venous oxygen desaturation persists. If a second apnea occurs within this interval, the slope of desaturation may be increased).

Using these parameters and realizations discussed supra, the inventor of the present invention made a system and technique which automatically analyzed the waveform pattern of continuous nocturnal oximetry, to specifically identify the presence or absence of moderate to severe obstructive sleep apnea-induced arterial oxygen desaturation. Such a system and technique makes it possible to diagnose moderate to severe obstructive sleep apnea with confidence with a single channel recording of nocturnal oximetry alone avoiding the need for complex and expensive polysomnography in the diagnosis of this disorder. The system and technique includes a mechanism to achieve the measurement of a compendium of parameters which are repetitively measured and analyzed, each improving the specificity of the diagnosis.

A summary of one such technique is as follows:

1. Dispose a microprocessor in connection with the oximeter with a probe and printer for recording the oxygen saturation of hemoglobin as a function of time.

2. Attach the oximeter probe to a patient.

3. Define a measurement interval.

4. Define the mean maximum baseline range of oxygen saturation of hemoglobin over the measurement interval.

5. Define a desaturation event as at a specific uninterrupted decrement in saturation below the defined baseline range of oxygen saturation.

6. Measure the duration of the uninterrupted decline in saturation of each desaturation event.

7. Calculate the descending slope of each desaturation event.

8. Define a resaturation event as an uninterrupted rise in saturation which terminates the declining slope of the desaturation event.

9. Calculate the ascending slope of each resaturation event.

10. Define a phasic desaturation event as all coupled desaturation and resaturation events wherein the sum of the duration of the desaturation event and the resaturation event is less than a specified value and wherein the descending slope falls within a finite range.

11. Calculate the descending to ascending saturation slope ratio of each phasic desaturation event.

12. Define the number of probable apneic events within the measurement interval by comparing said calculated slope with a value of slope which is determined in advance to be indicative of sleep apnea, using any of the above techniques.

13. Identify each probable apneic event with an identity marker, or alternatively mark each event by its descending slope or by the slope ratio.

14. Treat the sleep apnea, either automatically, or manually, based on a diagnosis.

15. Repeat steps 1-14 to confirm the diagnosis and efficacy of treatment.

The above system represents the general concepts of one embodiment of the present invention. Other comparisons which incorporate the desaturation slope and the resaturation slope are also included within this teaching.

For example figure 5 shows how a comparison can use the calculation of the area above each desaturation event compared to area above each coupled resaturation event. With this system, an x-axis is projected from a point of initial desaturation. A second y-axis is projected upward from the initial point of rise of saturation which signifies the onset of a resaturation event. The areas above the sloping lines, defined as D and R in the above figure, are then compared in a similar manner to that described in the previous embodiment.

In addition, the specificity and sensitivity of oximetry with respect to the diagnosis of sleep apnea is greatly enhanced by another embodiment of the invention which includes all of the multiple slope comparisons as described above. In such a system, in combination, the desaturation slope is compared to a desaturation slope which is consistent with a diagnosis of sleep apnea; second, the resaturation slope is compared with resaturation slopes known to be consistent with sleep apnea; third, desaturation

slopes are compared with coupled resaturation slopes to define a slope index which is known to be consistent with sleep apnea; fourth, desaturation slopes and resaturation slopes are compared with other such slopes within the same record to identify slope similarity of the desaturation slopes and slope similarity of the resaturation slopes, respectively; furthermore, the similarity of the desaturation-resaturation slope index of the identified events can be compared; furthermore, as previously discussed, consecutive slopes can be compared in relationship to the interval between desaturation events to determine whether a preceding desaturation event affects the slope of a closely after following desaturation event, and; finally, the mean of all desaturation slopes can be compared to the mean of all resaturation slopes to define an aggregate index.

In another embodiment, the present invention identifies a phasic desaturation event to trigger storage or collection of at least one additional parameter of the patient. These additional parameters can be, for example, a recording of sound or video. When the microprocessor identifies specific coupled desaturation-resaturation parameters which are physiologically consistent with sleep apnea, the microprocessor initiates the storage of selected data collected by at least one additional sensor.

Sound has been shown to be an important indicator of airway obstruction, however, many patients spend the majority of their night without major obstructive apneas. Therefore, if the entire night of sound were recorded, it would include a large amount of unnecessary sound recording, for only a

small amount of useful data surrounding obstructive apneas. In the preferred embodiment shown in Figure 1, the additional sensor includes a microphone 30 which can be integral with or carried by the probe 13 of the pulse oximeter 12 or which can be positioned in other regions near the patient during sleep. With this preferred embodiment, the microphone 30 is connected to an audio processor 32 of any known type, such as a Sound Blaster(TM) 16-bit processor. The sound is recorded digitally as a function of time. Alternately, the sound may be Fast Fourier transformed ("FFT"), and the transform information may be stored. Alternatively, other means of sound or other recording can be utilized.

Preferably, the sound is continuously recorded throughout the night and the most recent recording always maintained in short-term memory. If, after a finite period of time (for example, 4 minutes), no coupled desaturation-resaturation event occurs which is specific for sleep apnea, the oldest part of the recorded sound will be erased or otherwise not marked for retrieval. If, however, a coupled desaturation-resaturation event occurs which is consistent with sleep apnea, the identification of this event will trigger the marking and storage of the collected sound data during an interval preceding, during, and immediately after the event.

In the preferred embodiment, the total sound interval retained for each desaturation event includes the interval of the coupled desaturation-resaturation event, as well as one minute preceding and one minute following each such event; although this recording time can be further reduced for greater efficiency of

memory utilization. In this way, the entire night will be monitored by oxygen saturation while sound is stored, but the information can be rejected to save memory unless a sleep apnea event is identified by pulse oximetry. If a sleep apnea event is identified, this will trigger the long-term storage of sound information surrounding that event. In this way, the efficiency sampling of sound that can be greatly enhanced since only small portions of sound need be collected in relationship to each apnea event.

Continuous recording of oxygen saturation and sound when indicated as a function of time can be digitally stored on any commercially availible removable computer memory media, for example, a high-capacity floppy disc, or a removable Bernoulli disc, and then transported to a second microprocessor for evaluation by the physician and for printing. The entire record can be printed with a continuous graphical representation of oxygen saturation as a function of time. The sound can be graphically represented as a function of time by (for example, showing the volume as the width of the line and the frequency as its position along the y-axis). As discussed previously, such graphical representation of oxygen saturation can include specific markers indicating coupled desaturation and resaturation events which are physiologically consistent with sleep apnea.

Preferably, staccato or interrupted low frequency sounds may also be graphically represented preceding an oxygen desaturation event. Subsequently, variable high frequency sounds of low volume may be identified immediately preceding the recovery of

oxygen saturation, indicating the presence of post-apnea hyperventilation. The physician can easily, therefore, determine whether these oxygen desaturation events are due to obstructive sleep apnea by identifying the sound parameters with which these coupled desaturation-resaturation events are temporally associated. Of course, all coupled desatruation events might not necessarily be associated with a typical sound pattern. However, throughout the night recording, patients with obstructive sleep apnea would be expected to have typical snoring sounds; whereas, patients with central sleep apnea from a periodic breathing or alterations in ventilation-perfusion mismatch would not be expected to demonstrate such sound parameters in relationship to such coupled desaturation-resaturation events.

The system is further advantageous in that it allows the physician to efficiently focus on portions of the night which are of the greatest interest. For example, the physician can specify a desaturation event identified by the microprocessor as an apnea, then either look graphically at the sound surrounding that event or, alternatively, listen to digitally-recorded sound which surrounds a specific desaturation-resaturation event. It should also be clear that a video recorder could be activated in a similar manner, along with a sound recorder, to obtain critical bytes of a night's sleep for efficient evaluation. In this way, the diagnosis of airway obstruction can be confirmed, along with the diagnosis of sleep apnea, by utilizing a greatly simplified and

less expensive system than conventional home polysomnography.

While this language herein refers to oxygen saturation, it should be understood that this saturation could be determined in other ways than those specifically disclosed herein. For example, sequential and cyclic time-dependent storage of carbon dioxide in body compartments during sleep apnea can be similarly used to diagnose sleep apnea using, for example, the comparison of consecutive slopes of maximum exhaled p-CO

Many modifications will become evident to those skilled in the2art from this teaching and these modifications are included within the scope of this teaching.

WHAT IS CLAIMED IS:

1. A device for diagnosing sleep apnea, comprising:

means for determining an oxygen saturation of a patient's blood;

means for identifying a desaturation event, in which said oxygen saturation falls below a baseline level by a predetermined amount and for a predetermined time;

means for calculating a slope of said desaturation event representing a rate of change per unit time of fall of oxygen saturation; and

means for comparing said calculated slope with a value of slope which is determined in advance to be indicative of sleep apnea and making a diagnosis of sleep apnea based on said comparing.

2. An apparatus as in claim 1 wherein said slope is compared with an absolute number which is likely to indicate sleep apnea.

3. An apparatus as in claim 1 wherein said slope is compared with other slopes taken at different times.

4. An apparatus as in claim 1 wherein said desaturation event identified by said identifying means also includes a resaturation, immediately following said desaturation and coupled with said desaturation, in which the oxygen saturation rises, and wherein said determination is also based on a slope of said resaturation.

5. An apparatus as in claim 4 wherein said means for comparing includes means for calculating a ratio of resaturation slope to desaturation slope and comparing said ratio with a predetermined number to diagnose sleep apnea.

6. An apparatus as in claim 1 wherein said identifying means recognizes all events within a predetermined time period, and said calculating means calculates all slopes within said predetermined time period.

7. An apparatus as in claim 1 further comprising means for administering a therapy consistent with treatment of sleep apnea based on said diagnosis of sleep apnea.

8. An apparatus as in claim 1, wherein said comparing means includes means for analyzing a duration of the apneic episode and comparing said duration with a value of slope which is determined in advance to be indicative of sleep apnea to determine if it is of a duration likely to indicate sleep apnea.

9. An apparatus for diagnosing sleep apnea comprising:

a sensor of a type which determines an oxygen saturation of a patient's blood;

a microprocessor, programmed to recognize outputs from said sensor and to calculate an oxygen saturation of a patient's blood from said outputs, and

to recognize a desaturation event when said oxygen saturation falls a predetermined amount in a predetermined time and recognize a resaturation event when said oxygen saturation rises a predetermined amount in a predetermined time, said microprocessor also including means for comparing a slope of desaturation of said desaturation event with a slope of resaturation of said resaturation event, and using said comparison to diagnose sleep apnea.

10. An apparatus as in claim 9 further comprising means for applying a treatment effective to cure sleep apnea based on said diagnosis of sleep apnea.

11. A device for diagnosing sleep apnea, comprising:

means for determining an oxygen saturation of a patient's blood;

means for identifying a desaturation event at a first time, in which said oxygen saturation falls below a baseline level by a predetermined amount and for a predetermined time;

means for calculating a slope of said desaturation event representing a rate of change per unit time of fall of oxygen saturation; and

means for comparing said calculated slope with at least one other value of slope of another desaturation event at a different time than said first time, and making a determination of diagnosis of sleep apnea based on said comparing.

11. A device as in claim 1, further comprising means for storing other information in response to a determination of a desaturation event.

12. A device as in claim 11, further comprising a sensor, coupled to said comparing means, said comparing means controlling said sensor to store selected data upon a diagnosis of sleep apnea.

13. A device for diagnosing sleep apnea, comprising:

means for determining an oxygen saturation of a patient's blood;

means for identifying a desaturation event, in which said oxygen saturation falls below a baseline level by a predetermined amount and for a predetermined time;

means for continuously recording information from a patient; and

means for triggering a storage of said continuously recorded information for a predetermined time responsive to said identifying said desaturation event, and for otherwise commanding that said continuously recorded information not be stored.

FIG. 1

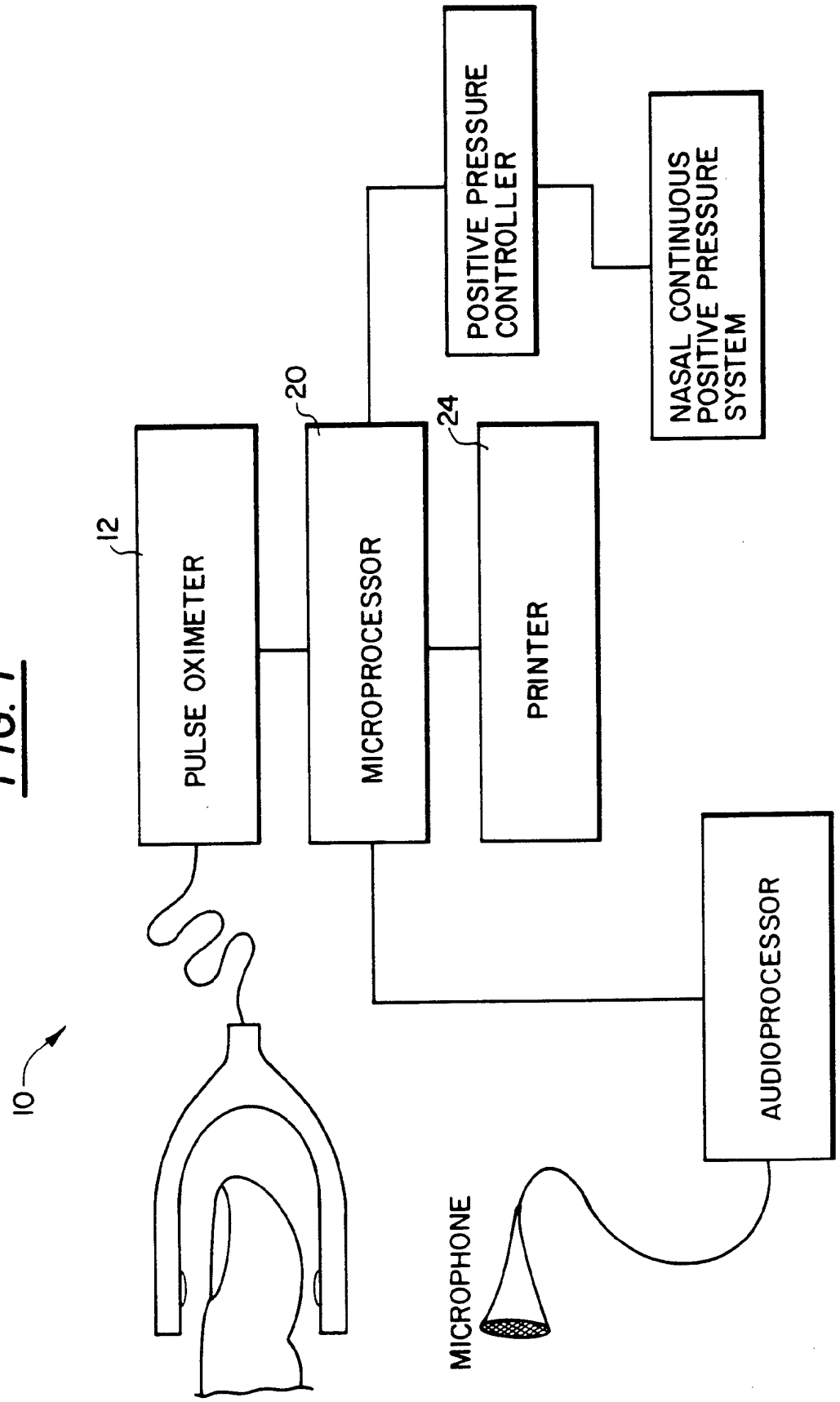

POSITIVE PRESSURE CONTROLLER
NASAL CONTINUOUS POSITIVE PRESSURE SYSTEM
20
24
12
PULSE OXIMETER
MICROPROCESSOR
PRINTER
AUDIOPROCESSOR
10
MICROPHONE

FIG. 2

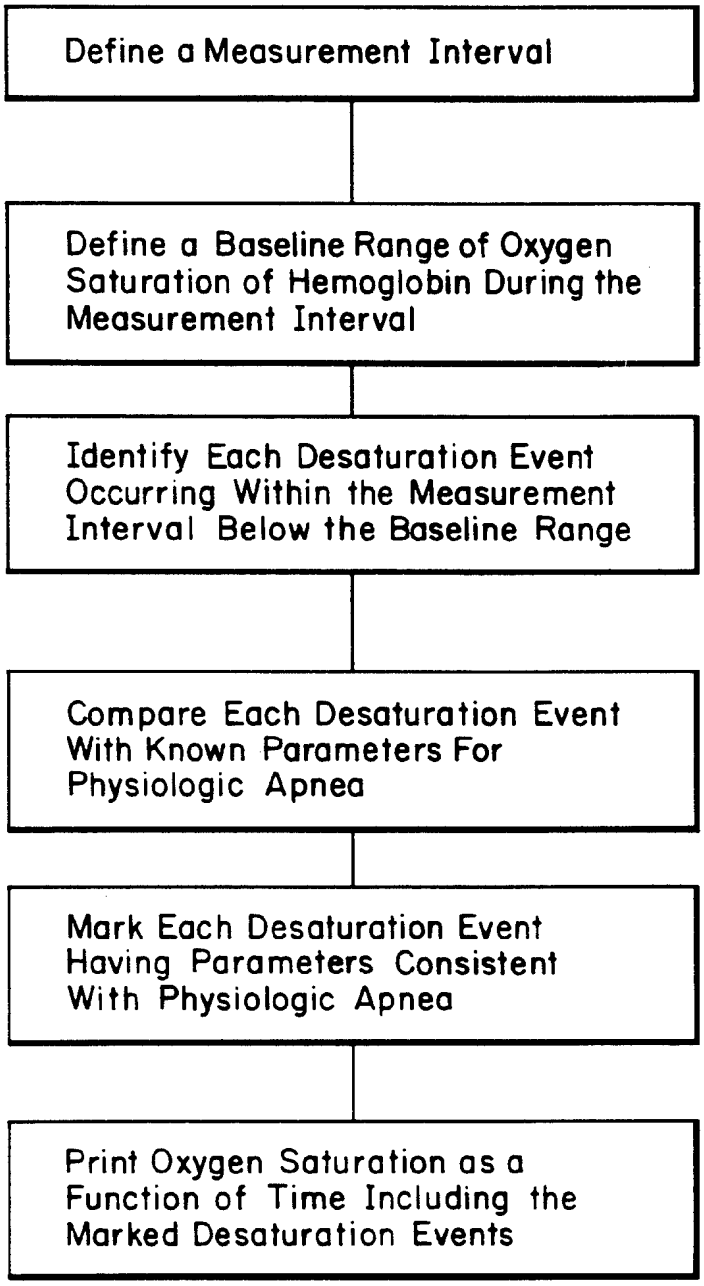

Define a Measurement Interval
Define a Baseline Range of Oxygen Saturation of Hemoglobin During the Measurement Interval
Identify Each Desaturation Event Occurring Within the Measurement Interval Below the Baseline Range
Compare Each Desaturation Event With Known Parameters For Physiologic Apnea
Mark Each Desaturation Event Having Parameters Consistent With Physiologic Apnea
Print Oxygen Saturation as a Function of Time Including the Marked Desaturation Events

FIG. 3

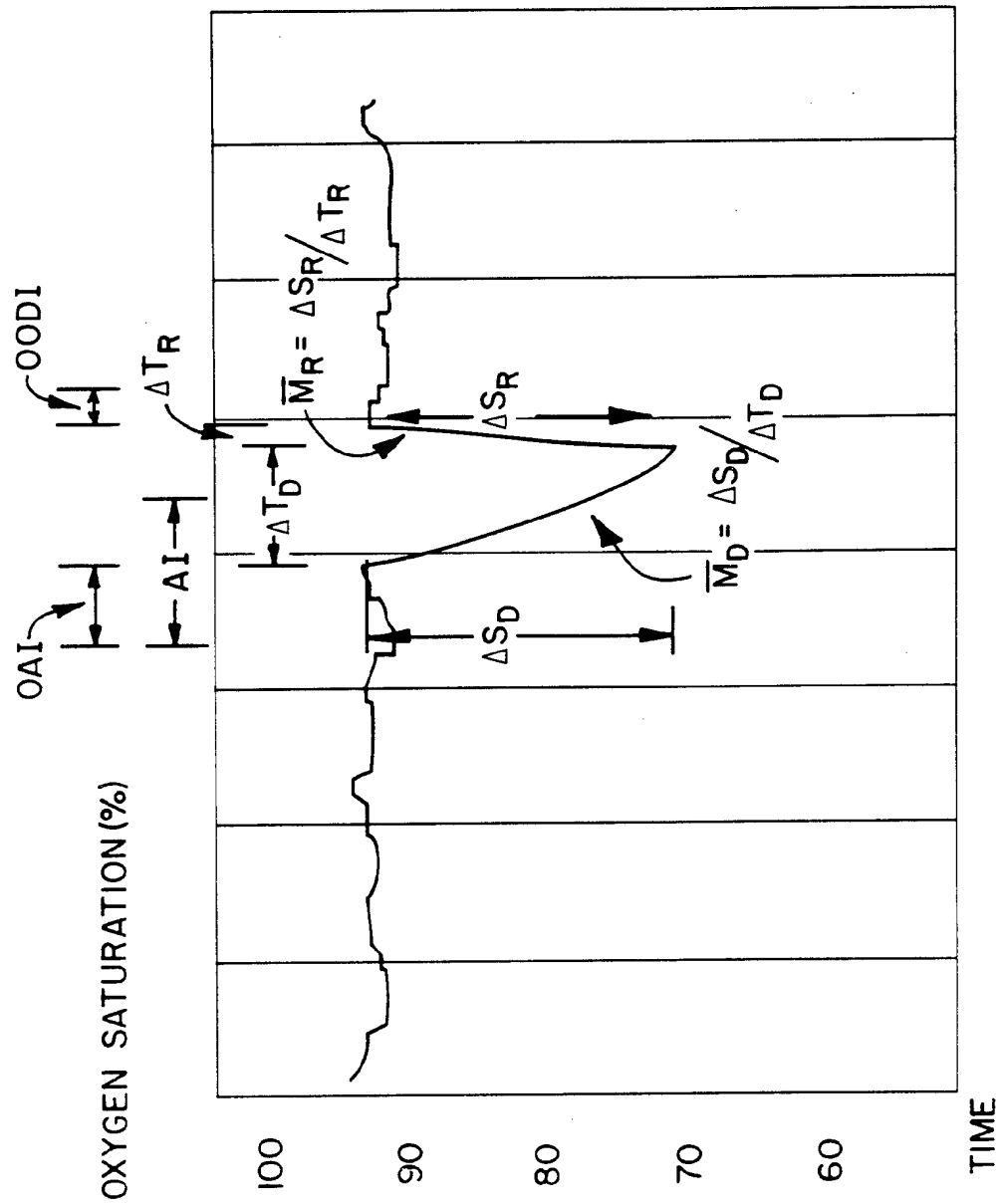

OODI
OAI
AI
ΔT_R
ΔT_D
$\overline{M}_R = \Delta S_R / \Delta T_R$
ΔS_R
ΔS_D
$\overline{M}_D = \Delta S_D / \Delta T_D$
OXYGEN SATURATION (%)
100
90
80
70
60
TIME

FIG. 4

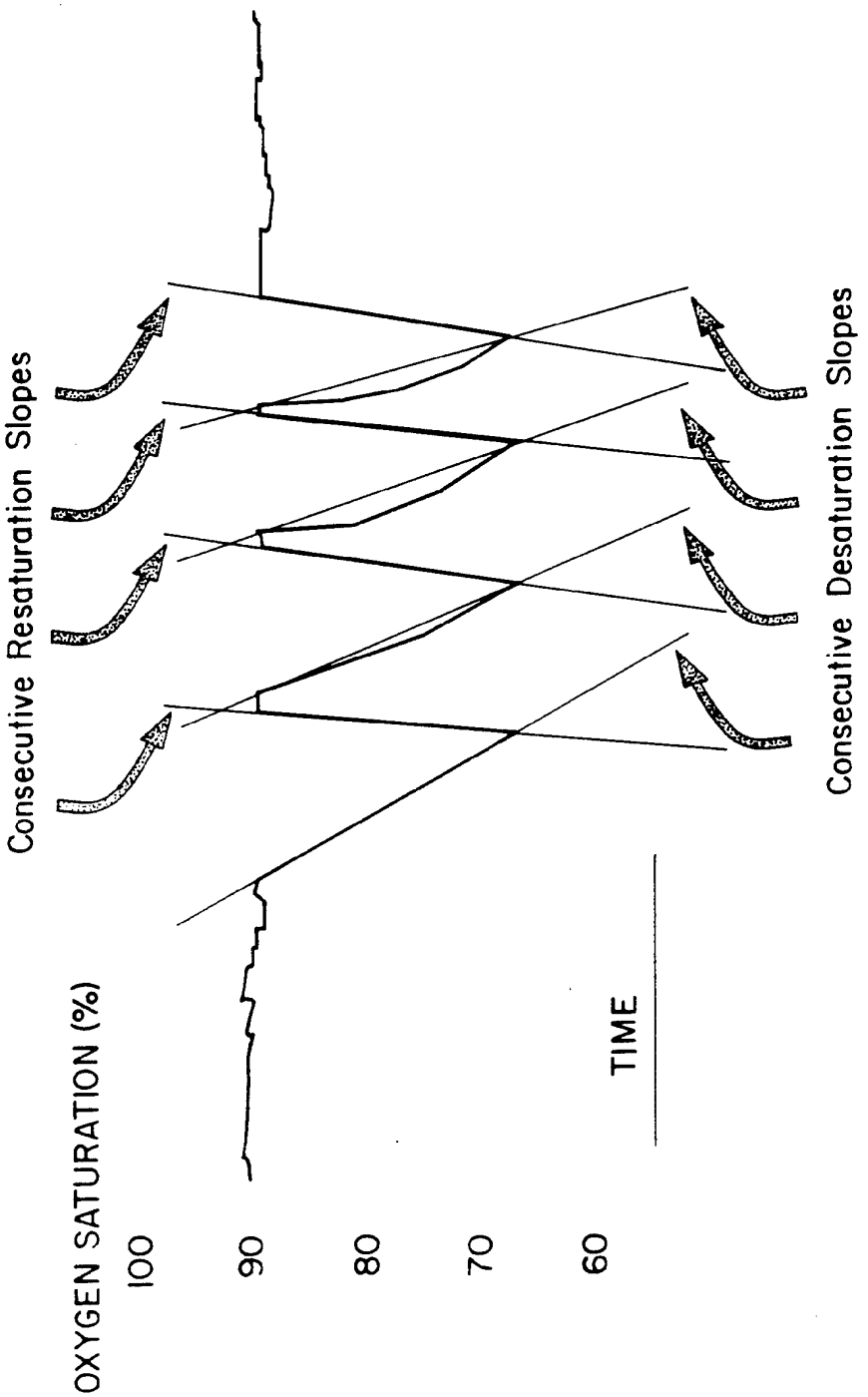
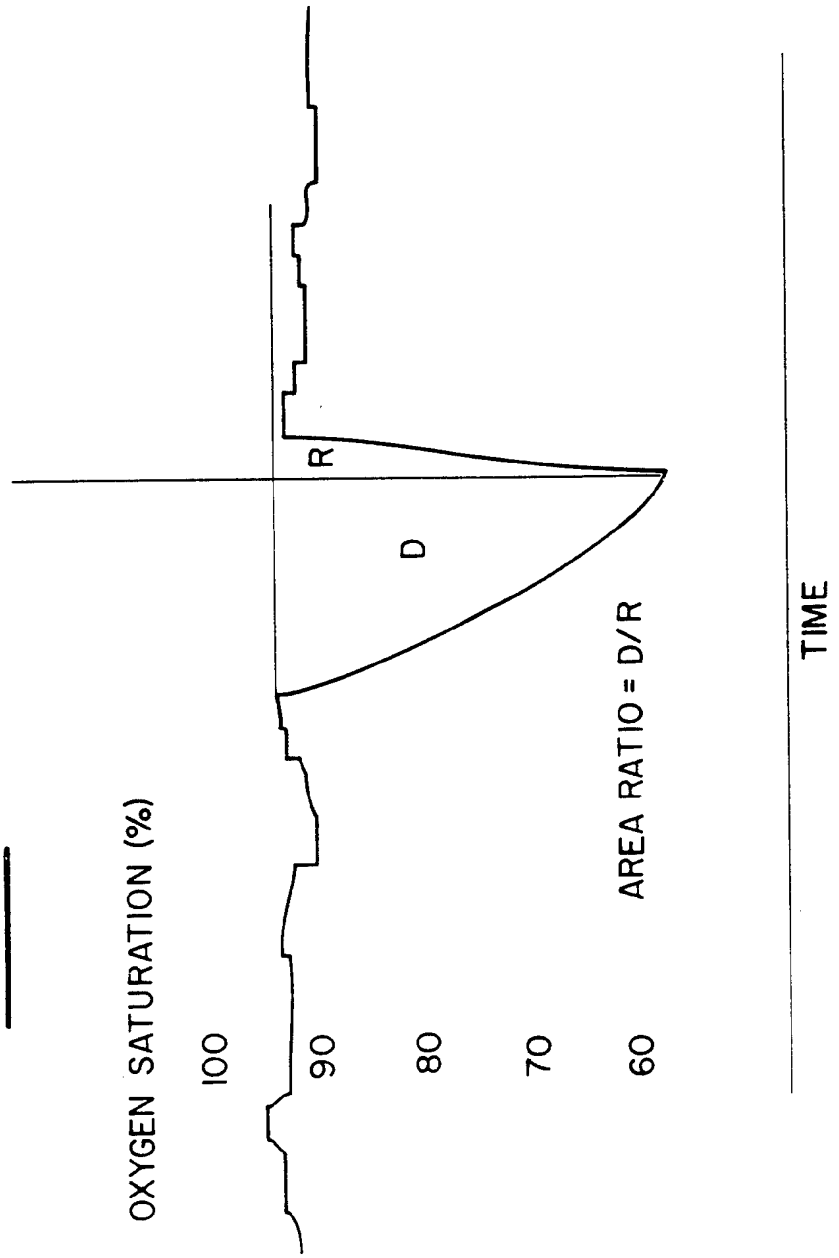

Consecutive Resaturation Slopes
Consecutive Desaturation Slopes
OXYGEN SATURATION (%)
100
90
80
70
60
TIME

FIG. 5



INTERNATIONAL SEARCH REPORT

Inte...ational application No.
PCT/US93/07726

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 5/00
US CL :128/633, 671, 716

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/633, 664, 665, 666, 667, 670, 671, 716, 719, 721, 722, 723, 724

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,630,614 (Atlas) 23 December 1986.	1-11
A	US, A, 4,757,824 (Chaumet) 19 July 1988.	1-11
A	US, A, 4,365,636 (Barker) 28 December 1982.	1-11
A	US, A, 4,738,266 (Thatcher) 19 April 1988.	1-11

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
20 SEPTEMBER 1993

Date of mailing of the international search report
15 DEC 1993

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